III. Provisions of this Final Rule -- Changes to the M+C Regulations

For the convenience of the reader, listed below are all significant changes to the M+C regulations that are set forth in this final rule. Please note that changes stemming from the BBRA, which--unlike those changes listed below--are subject to public comment, are all discussed in a discrete section of this preamble (section I.C) and thus are not listed here. In addition, we caution the reader that the list below is intended solely as a reference aid, rather than as a policy summary.

- In **§422.2**, we are revising the definition of "service area", as well as making minor technical changes to several other definitions.

- We are revising **§422.50**(a) to allow individuals and employer group members who become entitled to Medicare and live outside of the service area to convert to an M+C plan if they were previously enrolled in a commercial plan offered by the M+C organization, provided these individuals receive full plan benefits and M+C access and availability standards are met.

- To allow us the flexibility to vary the timeframes for the enrollment transmission schedule in the future, we are amending **§422.60**(e)(6) to state "upon receipt of the election form or from the date a vacancy occurs for an individual who was

accepted for future enrollment, the M+C organization transmits within time frames specified by HCFA, the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization."

- We are revising **§422.60**(f)(3) to state that "upon receipt of the election form from the employer, the M+C organization must submit the enrollment within time frames specified by HCFA."

- In order to avoid introducing confusion between responsibilities of M+C organizations and HCFA, we have eliminated material in **§422.64** concerning HCFA's information responsibilities and moved necessary material to §422.111.

- We have modified **§422.66**(b)(3)(i) to state that the timeframe to submit disenrollment transactions will be "specified by HCFA," and have made a conforming change at §422.66(f)(2), as opposed to within 15 days.

- At **§422.66**(d) we are clarifying that an M+C organization must accept any eligible individual who is enrolled in a health plan offered by "an" M+C organization to apply to a specific M+C organization, namely the organization that offers both the commercial health plan in which the individual is enrolled and the M+C plan in which the individual will be enrolling.

- At **§422.74**(b)(3)(ii) we are permitting an M+C organization that has reduced an M+C plan's service area to offer

continued enrollment in one of its M+C plans to enrollees in all or a portion of the reduced area if enrollees agree to receive "basic benefits" exclusively at designated facilities within the plan's new service area.

• We are adding a provision to **§422.74**(d)(1)(iv) that expressly provides an M+C organization the option to discontinue an optional supplemental benefit for which premiums are not paid, while retaining the beneficiary as an M+C enrollee.

• We are changing the requirement at **§422.74**(d)(4) to state that the M+C must disenroll an individual, unless he or she chooses the continuation option, if the individual moves out of the plan's service area for over 6 months, rather than 12 months.

• We are adding wallet card instructions to the list of examples of marketing materials at **§422.80**(b)(5)(v), to ensure that wallet card instructions to enrollees are consistent with the statute and regulations, particularly requirements that apply to emergency and urgently needed services.

• We are revising **§422.80**(e) to permit more flexibility for providers in distributing materials to M+C enrollees.

• We are adding a new **§422.80**(e)(1)(viii) that prohibits new M+C plan names that exclude the disabled population.

• We are removing the definition of post-stabilization services in **§422.100**(b)(1)(iv) and instead including all post-

stabilization requirements in new **§422.113.** See section II.C of this preamble for a full discussion of changes in the post-stabilization requirements.

• We are specifying at **§422.100**(b)(1)(vi) and §422.113 that M+C organizations are required to cover ambulance services dispatched through 911 or its local equivalent when use of other forms of transportation would endanger the health of the beneficiary.

• We are adding a provision at **§422.101(a)** to state explicitly that services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

• To promote beneficiary freedom of choice among providers, **§422.105** is revised to permit use of the POS option for in-network providers, rather than only for providers outside the plan network.

• To clarify our existing policy, we are clearly delineating HCFA's review authority in **§422.106** for employer group health plans and Medicaid plans.

• We are adding a new **§422.108(f)** to clarify that a State cannot take away an M+C organization's Federal rights to bill or authorize providers to bill for services for which Medicare is not the primary payer.

• We are revising **§422.109**(b)(5) to provide that M+C enrollees are responsible only for coinsurance amounts.

• We are revising **§422.111(e)** to decouple the enrollee notice time frame from the “issuance or receipt" of a notice of termination and instead require that an M+C organization make a good faith effort to provide written notice at least 30 calendar days before the termination effective date.

• We are revising **§422.112**(a)(3) to clarify that an M+C organization shall authorize out-of-network specialty care when its plan network is unavailable or inadequate to meet an enrollee's medical needs.

• At new **§422.113**(b) we are specifying that "urgently needed services" are not "emergency services."

• We are clarifying at **§422.113**(b)(2)(ii) that prior authorization may not be required from the beneficiary in wallet card instructions or in other enrollee materials . We are also specifying that instructions on what to do in an emergency should include a statement specifying that in the event of an immediate and serious threat to health, the enrollee may call 911.

• We are revising **§422.113**(b)(2)(iii) to expressly set forth the requirement that M+C organizations assume financial responsibility for services meeting the prudent layperson definition of emergency at §422.2 regardless of final diagnosis.

• In order to clarify the distinction between a removal of deemed status by HCFA based on HCFA's own survey and a removal based on a determination by an accreditation organization based on its accreditation survey, we are revising **§422.156**(a) to separate these two situations.

• We are revising **§422.157**(a)(3) to relax the prohibition on the participation of managed care organization representatives in private accreditation organization activities.

• We are revising **§422.158**(e) to provide that we will act within the same timeframes that apply to fee-for-service deeming.

• To help clarify that the appeals procedures apply only for adverse participation decisions, we are redesignating the provider appeals procedures from §422.204(c) to new **§422.202**(d).

• Section **422.204** has been re-titled "Provider selection and credentialing" and contains the general rule that an organization must have written policies and procedures for the selection and evaluation of providers.

• We are consolidating the regulations concerning antidiscrimination and choice of providers into new **§422.205.** We reaffirm that M+C organizations are prohibited from discriminating against providers based solely on their licensure or certification, and specify that when an M+C organization

declines to include a provider in its network, it must notify the provider of the reason for its decision.

- We have revised **§422.214** to clarify the rules concerning payments to noncontracting providers.

- We have revised **§422.216**(f) to indicate that, for PFFS purposes, "deemed contract" providers are considered to be noncontracting providers when they furnish services in an emergency department of a hospital.

- We are revising **§422.257** to permit M+C organizations to require that their contractors provide them with complete and accurate encounter data.

- We are adding two terms -- "first tier" and "downstream" -- to the list of definitions at **§422.500** that we believe clarify the types of entities to which the M+C contracting requirements described at §422.502(i) apply.

- We are revising the definition of "clean claim" in **§422.500** to require that claims include data for encounter data submission, and meet the original Medicare "clean claim" requirements in order to be considered a clean claim.

- In consultation with the Office of Inspector General, we are revising the compliance plan requirements under **§422.501** to eliminate mandatory self-reporting.

• In order to ensure that M+C enrollees are not put at financial risk in situations where provider groups or other entities "downstream" from an M+C organization become insolvent, we are revising **§422.502** to strengthen the protections for Medicare enrollees in situations where an M+C organization or its contractors encounter financial difficulties.

• Section **422.502**(l), concerning certifications of the accuracy of payment data, has been modified to be consistent with the OIG's "good faith" standard, under which M+C organizations certify the accuracy of payment information to their "best knowledge, information, and belief." We are also permitting the delegation of this responsibility to individuals other than the CEO or CFO of the M+C organization.

• We are revising **§422.506**(a)(2)(i) to permit an M+C organization until July 1 to notify us of its intent not to renew its M+C contract for the upcoming contract year.

• We are deleting **§422.506**(b)(ii) in response to a concern that the standard for declining to renew an M+C contract was too vague to enforce.

• We are adding a new **§422.510**(a)(12) that would specify that a substantial failure to comply with marketing guidelines is grounds for termination, non-renewal, or intermediate sanction.

• We are changing the language at section **§422.520**(a)(3) to indicate that non-clean claims and the remaining 5 percent of clean claims not paid within 30 days must be either paid or denied within 60 calendar days from the date of the request.

• We are revising the definition of an organization determination under **§422.566** to provide additional clarity as to the types of situations that constitute an organization determination and thus give rise to the pursuant appeal rights.

• To further clarify the grounds on which an M+C organization may seek an extension, and to ensure an enrollee is adequately advised of the M+C organization's use of an extension, we are adding language to both **§§422.568(a)** and **422.572(b)** that requires an M+C organization to notify the enrollee in writing of the reasons for the extension, and to inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision.

• We are revising **§422.568(c) and (d)** to modify the requirement concerning written notification of M+C enrollees when a service is denied in whole in or part.

• We have added new **§422.619** concerning effectuation of expedited reconsideration determinations.

• We have revised **§422.620** to eliminate the requirement that M+C organizations distribute to enrollees the notification of noncoverage of inpatient hospital care.

We have also made many minor technical and conforming changes to the M+C regulations to ensure that citation references are accurate, use more consistent terminology, and correct typographical errors in the current regulations.

IV. Collection of Information Requirements

Under the PRA, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the sections that contain information collection requirements.

Note: Unless otherwise noted below, all information collection requirements in this rule are currently approved under OMB approval #0938-0753, which currently expires August 31, 2000.

Section 422.60 Election process.

Paragraph (b) of this section states that M+C organizations may submit information on enrollment capacity of plans they offer by July 1 of each year as provided by §422.306(a)(1). The burden associated with this reporting provision is captured under §422.306.

Section 422.74 Disenrollment by the M+C organization

Paragraph (c) of this section requires that if the disenrollment is for any reason other than death or loss of entitlement to Part A or Part B, the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must include an explanation of the individual's right to a hearing under the M+C organization's grievance procedures. This requirement is currently approved under 0938-0763, which expires March 31, 2003.

Section 422.111 Disclosure requirements

Paragraph (e) requires the M+C organization to make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days (revised from 15 days) before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The burden associated with this requirement has not changed.

Section 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services

Paragraph (b)(2) of this section requires that enrollees be informed of their right to call 911.

The burden associated with this disclosure provision is the time it takes an M+C organization to inform each beneficiary of his or her right. In addition, instructions to seek prior authorization for emergency services and/or before the enrollee has been stabilized may not be included in any materials furnished to the enrollee. We anticipate that these requirements will be provided as part of standard enrollment disclosures. Therefore, the burden associated with this requirement is contained in section 422.64.

Section 422.152 Quality assessment and performance improvement program

Paragraph (e) of this section requires that an organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan to measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA and will relate to clinical areas including effectiveness of care, enrollee perception of care, and use of services and to nonclinical areas

including access to and availability of services, appeals and grievances, and organizational characteristics.

The burden associated with this reporting provision is the time it takes an M+C organization to gather and submit the information. "All Medicare+Choice organizations and an organization offering an M+C non-network MSA plan or an M+C private fee-for-service plan will be required to measure performance under their plans, using standard measures required by HCFA, and report their performance to HCFA. Reporting will be required annually. Currently the standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB # 0938-0701. The currently approved annual per plan burden is estimated to be 400.53 hours. Therefore, the total burden associated with this requirement is 180,239 hours (400.53 hours x 450 plans (100 new/350 current)).

Section 422.202 Participation procedures

Paragraph (d) of this section requires that an M+C organization that suspends or terminates an agreement under which the physician provides services to M+C plan enrollees give the affected individual written notice as required by this section.

This section also requires that an M+C organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care give written notice of that

action to licensing or disciplinary bodies or to other appropriate authorities.

The burden associated with these reporting provisions is the time it takes an M+C organization to write the notice and give it to the practitioner and the appropriate licensing, or disciplinary bodies or to other appropriate authorities. We estimate that it will take 450 plans, 10 hours to produce and disclose 10 notices on an annual basis, for a national annual burden of 4,500 hours.

In addition this paragraph requires that an M+C organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

The burden associated with this reporting provision is the time it takes an M+C organization and provider to write the notice and furnish it to the other party. We estimate that 450 entities will be required to write 10 notices, at 1 hour per notice, for a national annual burden of 4,500 hours.

Section 422.205 Provider antidiscrimination rules

The reporting requirement of this section requires that, if an M+C organization declines to include a given provider or group of providers in its network, it furnish written notice to the affected provider(s) of the reason for the decision.

The burden associated with this reporting provision is the time it takes an M+C organization to write and provide the required notice. We estimate that it will take 450 plans, 30 minutes to produce and disclose 20 notices on an annual basis, for a national annual burden of 4,500 hours.

Section 422.206 Interference with health care professionals' advice to enrollees prohibited

The reporting requirement in paragraph (b)(2) requires that, through appropriate written means, an M+C organization make available information on any conscience protected policies to HCFA, with its application for a Medicare contract, within 10 days of submitting its ACR proposal or, for policy changes, in accordance with §422.80 (concerning approval of marketing materials and election forms) and with §422.111. With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice within 90 days after adopting the policy at issue.

The revision to the information collection provisions requires the M+C organization to make available policy changes. We estimate that it will take 30 minutes for each of the 450 M+C organizations to comply, for a total of 2,225 hours nationally on an annual basis.

Section 422.257 Encounter data

Paragraph (d)(1) of this section requires that M+C organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service, when appropriate, and to all relevant national standards. M+C organizations must obtain the encounter data required by HCFA from the provider, supplier, physician, or other practitioner that rendered the services. In addition, M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate encounter data as required by HCFA.

The burden associated with this paragraph is currently approved under OMB approval # 0938-0753.

Section 422.568 Standard timeframes and notice requirements for organization determinations

Under paragraph (a) of this section, when a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee. When the M+C organization extends the

timeframe, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

The revision to this provision is that requiring the M+C organization to notify the beneficiary of its reasons for delay and of the right to file a grievance.

We estimate that this requirement will add 40 hours for each of the 450 M+C organizations to the burden currently captured under 0938-0753, for an annual addition of 18,000 hours.

Under paragraph (c), at each patient encounter with an M+C enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed notice from the M+C organization regarding the enrollee’s services. The practitioner must provide the enrollee with complete information, using approved notice language in a readable and understandable form, necessary to contact the M+C organization.

The burden associated with this reporting provision is the time it takes a practitioner to notify the beneficiary. We estimate that there will be 160 encounters per entity (450) and

that each notification will take an average of 15 minutes to do so, for a national annual burden of 4,500 hours.

Under paragraph (d), if an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

In addition to the currently approved burden under 0938-0753, the burden associated with this reporting provision is the time it takes to write the detailed decision and provide it to the beneficiary. We estimate that there will be 160 occasions per entity (450)for which a detailed decision must be provided and that each notification will take an average of 15 minutes for a national annual burden of 4,500 hours.

Under paragraph (e), the notice of any denial under paragraph (d) of this section must, in addition to currently approved requirements, (1) for service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and (2) for payment denials, describe the standard reconsideration process and the rest of the appeal process.

The burden associated with this reporting provision is the time it takes an M+C organization to add the required information to a notice. We estimate that it will take 450 plans 1 hour to produce and disclose the necessary language on an annual basis, for a national annual burden of 450 hours.

Section 422.570 Expediting certain organization determinations

The information collection requirement in this section ((d)(2)(iii)) that is not currently approved under 0938-0753 requires that, if an M+C organization denies a request for expedited determination, it must take give the enrollee prompt oral notice of the denial and subsequently deliver, within 2 calendar days (proposed as 2 working days), a written letter that informs the enrollee of the right to resubmit a request for an expedited determination with a physician's support. The currently approved burden, associated with this requirement has not changed.

Section 422.572 Timeframes and notice requirements for expedited organization determinations

The information collection requirement change to paragraph (b) requires that, when the M+C organization extends the deadline, it notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension.

The additional burden associated with this requirements set forth in this section is the time it takes an M+C organization to notify the beneficiary of the delay and the reasons for it. We estimate that 450 plans will provide extension notices to approximately 100 of their M+C enrollees on an annual basis and it will take an average of 5 minutes per notification. Therefore, the annual national burden is estimated to be 3,750 hours.

Section 422.584 Expediting certain reconsiderations

The information collection change to this section requires that, if an M+C organization denies a request for expedited reconsideration, it must give the enrollee prompt oral notice, and subsequently deliver, within 2 calendar days, a written letter that (in addition to currently approved disclosure requirements) informs the enrollee of the right to resubmit a request for an expedited reconsideration with a physician's support.

The one time burden associated with this disclosure requirement is the time it takes an M+C organization to add the requisite language to the letter it furnishes to the beneficiary. We estimate that it will take each M+C organization (450) an average of 30 minutes to add the language to its current letter for notifying beneficiaries, for a national annual burden of 2,250 hours.

§422.620 How enrollees of M+C organizations must be notified of noncoverage of inpatient hospital care.

The information collection change to this section the clarification that in all cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, the hospital (as provided under paragraph (d) of this section) or M+C organization must provide written notice to the enrollee that includes the elements described in this section. The burden associated with this requirement is currently approved and captured under 422.622.

We have submitted a copy of this final rule to OMB for its review of the revised information collection requirements in §§422.60, 422.74, 422.111, 422.113, 422.152, 422.205, 422.206, 422.257, 422.568, 422.570, 422.572, 422.584, and 422.620. These revised requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of this publication date directly to the following:

Health Care Financing Administration,

Office of Information Services,

Information Technology Investment Management Group,
Division of HCFA Enterprise Standards,
Room N2-14-26, 7500 Security Boulevard,
Baltimore, MD 21244-1850.
Attn: John Burke HCFA-1030-FC.

And, Office of Information and Regulatory Affairs,
Office of Management and Budget,
Room 10235, New Executive Office Building,
Washington, DC 20503,
Attn: Allison Heron Eydt, HCFA Desk Officer.

V. Regulatory Impact Statement

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and most other providers and suppliers

are small entities, either by nonprofit status or by having revenues of $5 million or less annually.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

As a result of changes to the M+C regulations to reflect provisions of the BBRA, this rule has been determined to be a major rule as defined in Title 5, United States Code, section 804(2). We consider a major rule to be one with economic effects of $100 million or more in a given year, and as noted below in section V.B.8 of this regulatory impact analysis, the effects of the BBRA changes reach this threshold. Generally, a major rule takes effect 60 days after the date the rule is published in the **Federal Register.** In this case, however, as discussed in detail above in section I.C of this preamble, the BBRA included specific effective dates for its various M+C provisions. For the most part, the statutory changes are self-explanatory, and have already taken effect. Thus, except as provided under the BBRA, the provisions of this final rule with

comment period take effect 30 days after publication in the **Federal Register.**

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more. This final rule with comment period will have no consequential effect on State, local, or tribal governments. We believe the private sector cost of this rule falls below these thresholds as well.

1. Summary of the Final Rule

As discussed in detail above, this rule implements only limited changes in the M+C regulations published June 26, 1998 (and further amended February 17, 1999). While we do not expect the changes contained in this final rule to have a significant economic impact, we believe that we have a responsibility to keep the public informed of the impact of inherent features of the M+C program, such as payment changes and the implementation of risk-adjusted payments. We attempted to describe the impacts of these payment changes in the interim final rule. However, after a year of experience administering the program, we now have a better understanding of the impact of the payment changes. This impact analysis will examine payment effects associated with these two

items, and respond to public comments concerning the economic impact of M+C policies.

2. Summary of Comments on Impact of M+C Program

Although commenters on the interim final rule generally recognized that the payment methodology and rates associated with the M+C program were implemented as directed by the BBA, several commenters still expressed concern that resulting payments to M+C organizations were insufficient to keep pace with the costs of providing medical care. These commenters suggested that the new payment methodology, particularly when combined with the implementation of a risk adjustment mechanism in 2000, could have the unintended consequence of limiting, rather than expanding, the health plan choices available to Medicare beneficiaries. M+C organizations have withdrawn from some areas, and many beneficiaries have experienced growing premium increases or benefit reductions. Commenters also asserted that the M+C regulations contained discretionary provisions that added unnecessarily to the administrative burden on M+C organizations. In particular, commenters identified quality standards, provider participation requirements, and attestation procedures as examples of what they considered overly proscriptive rules that had the potential to raise health plan costs. In general, commenters urged us to evaluate more carefully the cumulative impact of the changes introduced by the M+C program.

We noted in our February 17, 1999 limited M+C final rule that we needed a statistically-based model to evaluate the total impact of payment changes for M+C organizations. We have subsequently developed a model that estimates the impact of risk-adjusted payments on M+C organizations. This impact analysis focuses on results from this model. When possible, we provide detail on impacts by geographic area and by organization size.

We then discuss some of the concerns raised by commenters about likely withdrawals from the M+C program. Finally, our analysis examines available information concerning the administrative burden associated with selected M+C requirements.

B. Payment Changes

1. Background

Prior to the BBA, Medicare's capitation rates for managed care plans had been set at 95 percent of expected costs based on actual fee-for-service costs. Because of the variation in fee-for-service expenditures for different counties due to different utilization patterns and cost structures, the Medicare managed care rates for different counties were also quite divergent. In addition, there was significant evidence that Medicare had paid more for enrollees in the Medicare managed care programs than it would have paid in the fee-for-service program. This was due primarily to the favorable selection that these plans have experienced.

The BBA made a number of changes in Medicare payments to managed care plans including:

C Increasing payments in counties that historically had the lowest payment rates (and generally have not had risk-based Medicare managed care plans) through the use of a payment floor and by introducing a blended payment rate.

C Reducing the rate increases in counties that historically had higher payment rates.

C Reducing M+C capitation rates by phasing in the removal of direct and indirect medical education payments from M+C capitation rates beginning in 1998, (and phasing in direct payment of these "carved out" amounts to the institutions providing care to M+C enrollees).

Payment increases from year to year after 1997 are based on an update factor that is the rate of increase in projected Medicare expenditures each year, less a statutorily specified reduction (reducing the rate to .8 percent less in 1998 and .5 percent less each year thereafter through 2002). However, all counties are guaranteed a minimum payment increase of 2 percent over the preceding year's base rates.

The BBA also mandated the introduction, by the year 2000, of risk-adjusted payments in the M+C program. Risk adjustment will have the effect of reducing payments to plans because, as a number of studies have shown, relatively healthier Medicare

beneficiaries enroll in M+C plans. Projections on reduced payments assume a stable mix of enrollees. However, we assume that organizations will respond appropriately to the incentives to attract more seriously ill beneficiaries. As a result, organizations can do better under risk adjustment than they would if case mix stayed the same.

These M+C payment changes were intended to promote the three objectives which we discuss below in V.B.2, 3 and 4.

2. Promote the Availability of M+C Plans in Lower Payment Areas

The introduction of a "floor" on the payment rates for M+C organizations was intended to make the program financially viable in areas where the AAPCC appeared to be too low for any organization to recoup its costs. Beginning in 1998, the floor was set at $367 and was adjusted annually by the rate of growth of the overall Medicare program. By providing this floor payment level, M+C organizations are paid more than would otherwise be spent on the same beneficiaries in original Medicare.

Some county payment rates are raised through implementation of blended payments. These rates are calculated as a blend of national average rates adjusted for local input prices and area-specific rates. Area-specific rates are 1997 payment rates, adjusted for spending for graduate medical education, and updated using the national M+C update factor.

By raising the M+C payment levels higher than the spending amounts in original Medicare, it was hoped that M+C organizations would be attracted to these lower payment areas. In the chart below, we have compared the M+C county payment rates for 2001 to the area-specific rate in each county. In 2001, 3,020 counties will receive a payment rate higher than their area-specific rate. The payment rate for Arthur, Nebraska, will be 77 percent or $175 higher, the greatest improvement for any county.

The payment floor and the phased in blended payments were also designed to raise the payment level for more than just the lowest payment counties. Raising payments above the levels determined by the pre-BBA methodology was intended to give organizations that have operated in lower payment counties the opportunity to enhance their benefit packages, thereby increasing enrollment.

The largest improvements in payments are for areas with relatively small numbers of beneficiaries, and are largely achieved in most cases by applying the payment floor. Many more beneficiaries live in counties where the improvements are more modest (up to a 5 percent difference). These counties were primarily those paid under the blend mechanism in 2000, whose payment improvements were safeguarded by the minimum increase component of the formula for 2001.

Following is a breakout of the 3,147 U.S. counties by percentage improvement over their area specific rate:

Table 1

Percent Difference Between M+C Payment Rates and Area-Specific Payment Rates, 2001

Percentage Difference	Number of Counties	Number of Beneficiaries (000s)	Payment is Floor	Payment is Blend	Payment is Minimum Increase
Negative	127	1,318	0	0	127
0 to 5	1000	15,741	0	0	1000
5 to 10	946	9,848	62	0	884
10 to 20	572	4,133	401	0	171
20 to 30	264	888	264	0	0
30 to 40	131	408	131	0	0
40 to 50	68	142	68	0	0
50 to 60	26	52	26	0	0
60 to 70	9	18	9	0	0
70 to 80	4	5	4	0	0
Total	3,147	32,554	965	0	2,182

SOURCE:HCFA,CHPP.

Counties where M+C payment rates are lower than their area-specific payment rate tend to be those that have received the minimum increase for each of the four years that the M+C payment formula has been in place, and also had relatively little medical education spending. The cumulative four-year increase of the national update was approximately 9.3 percent, only a percentage

point higher than the cumulative four-year increase of 8.2 percent for those counties receiving the minimum update each year. The area-specific payment rate in 2001 reflects a reduction to the 1997 rate of 80 percent of spending attributable to medical education. Thus, a county with relatively high medical education spending will have a higher M+C payment rate than area-specific payment rate even if it also had received the minimum update each year.

3. Reduce the Wide Disparities in Payments between High and Low Payment Areas

By changing how payment rates are calculated, the BBA also sought to even out the wide disparity in Medicare managed care payment rates across counties, an issue that had been a concern for lower-payment areas. Table 2 shows the percentage of counties that received the floor, a blended rate, or the minimum 2 percent increase for each year calculated using the BBA methodology.

Table 2

Percent of Counties Receiving Floor, Blend, or 2 Percent Increase

Year	Floor Counties	Blend Counties	2 Percent Counties
1998	33.8%	00.0%	66.2%
1999	39.7%	00.0%	60.3%
2000	29.1%	63.1%	7.8%
2001	30.7%	00.0%	69.3%

Source: HCFA, CHPP

There were only limited payment increases for 1998 and 1999, with counties receiving either the floor payment or the minimum 2 percent update. This was due primarily to the combined effects of the amount of the national update and the budget neutrality provision affecting calculation of the blended rate. In 2000, however, well over half the counties are receiving the blended rate. The enrollment-weighted average increases in M+C payments nationwide in the year 2000 over 1999 is slightly more than 5 percent. For 2001, all counties will receive the floor payment or the minimum 2 percent update, again because of the budget neutrality provision and a national update that reflects the extremely low rate of spending in original Medicare in 1999. Although most counties will receive the minimum increase in 2001, many of these had enjoyed relatively large increases due to the

blended rates in 2000, which the minimum increase essentially will preserve.

As illustrated in the graph below (1997 Medicare+Choice Payment Rates Compared with 2001 Payment Rates), the new payment formulas have changed the distribution of payment rates across counties, although perhaps not as quickly as the Congress envisioned because of the unusually low national increases in spending. In 1997, county payment rates for aged beneficiaries ranged from $221 to $767. Through the implementation of the payment floor, blended payment rates, and minimum update, payments have increased substantially at the low end of the distribution, and increases at the high end have slowed. The range of payment rates in 2001 is only somewhat smaller: between $415 and $831, but the 2001 payment curve is straighter than the 1997 curve, indicating a narrower distribution.

Graph

Source: HCFA, CHPP

While national numbers show the overall pattern, the impact is highlighted when examining the effect of the BBA on the

payment rates at the State level. Table 3 shows the effect of the payment changes in two States: Oregon and Florida. Both States have significant M+C enrollment penetration, but Oregon's rates are low, and Florida's are high.

The BBA payment changes have narrowed the regional difference. In 1997, prior to the BBA payment changes, Florida's weighted average payment rates were 149 percent higher than those of Oregon. (Florida's statewide average payments were at 114 percent of the national average, while Oregon's were at 76 percent.) In 2001, Florida's rates will be 136 percent of Oregon's, because many Oregon counties had benefited from blended payment rates in 2000, while many large Florida counties received the minimum update that year.

Lower-paid States such as Oregon receive relatively higher rates of payment increases than higher-paid States such as Florida. These differential payment increases will bring both States' average payments closer to the national average payment rate.

Table 3

Comparison of Medicare+Choice Payment Rates in Oregon and Florida

State	Weighted Average Payment Rate 2001	Weighted Average Payment Increase 97-01	Payment Rate as a Percent of National 1997	Payment Rate as a Percent of National 2001
Oregon	$435.25	22.5%	76%	83%
Florida	581.15	9.6%	114%	111%
National	523.85	12.4%	100%	100%

Despite the BBA changes, the levels of benefits and premiums between higher and lower payment counties continue to vary in 2000. In Oregon, for example, premiums range from $35 to $83 for benefit packages that do not include outpatient drug coverage, and between $81 and $123 for packages including drug coverage. In Florida the enrollment-weighted average monthly premium is $84 per month, and all enrollees in Florida M+C plans have drug coverage in their basic package. Over time, the BBA payment changes may narrow this difference.

4. Establish a Fairer Payment System

The BBA mandated that we "implement a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payment [to M+C organizations] starting no later than January 1, 2000." The BBA also gives us the authority to collect inpatient hospital

data for discharges occurring on or after July 1, 1997, and allows us to require additional data from M+C organizations for services occurring on or after July 1, 1998.

a. Description of the Inpatient Risk Adjustment Model

In implementing the BBA mandate, we selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method to implement in 2000. Under the PIP-DCG model, individuals are assigned to a single PIP-DCG group based on the principal inpatient diagnosis they were assigned during an inpatient stay, that has the greatest future cost implications. The model is prospectively based; in other words, base year inpatient diagnoses are used in the model to predict payment year health expenditures. The model also uses age, sex, original reason for Medicare entitlement (such as age or disability), and entitlement to state payments for Medicaid to derive a predicted expenditure level. This predicted expenditure amount is then converted to beneficiary relative risk factors by dividing an individual's predicted expenditures by the national mean. Because this model was developed and calibrated using a year of inpatient diagnoses, a full year of data is essential for assigning beneficiary risk factors. Beneficiaries "new" to Medicare (for whom no prior diagnosis information exists) have their payments based on the average expenditures for their age group. To determine risk adjusted monthly payment amounts for each M+C

enrollee, individual risk factors will be multiplied by the appropriate payment rate for their county of enrollment.

We decided to include a transition period as a component of our risk adjustment methodology, initially using a blend of payment amounts under the current demographic system and the PIP-DCG risk adjustment methodology. Under a blend, payment amounts for each enrollee will be separately determined using the demographic and risk methodologies (that is, taking the separate demographic and risk rate books and applying the demographic and risk adjustments, respectively). These payment amounts would then be blended according to the percentages for the transition year. This transition to full risk adjusted payment will be phased in over 5 years. Following is the transition schedule to comprehensive risk adjusted payment as mandated by the BBRA:

Calendar Year	Demographic Method	PIP-DCG Method
2000	90 percent	10 percent
2001	90 percent	10 percent
2002	80 percent	20 percent

b. Impact of Risk Adjustment

The impact analysis presented here employs a "point in time" approach. To estimate the payment impact of the risk adjustment change, we compared actual demographic-based payments to

estimated risk adjusted payments for the exact same enrollees for September 1998. Aggregated to the M+C organization level, the difference in these amounts represents a reasonable estimate of change in payment due to risk adjustment. Projections on reduced payments assume a stable mix of enrollees. However, we assume that organizations will respond appropriately to the incentives to attract more seriously ill beneficiaries. As a result, organizations can do better under risk adjustment than they would if case mix stayed the same.

This analysis uses the best data available at this time. The data to be used for actual payments (beginning January 1, 2000) will be based on hospital discharge data for the calendar year beginning on July 1, 1998 and ending June 30, 1999. The actual impact of the risk adjustment system relative to the current demographic system at the time of implementation may differ, due primarily to potential changes in M+C organization enrollment profiles and possible improvement in the quality and completeness of M+C organization data.

The impacts presented here show estimated figures for both the full effects of the PIP-DCG based payment system (that is, with no transition period), and for the first implementation year during which a 10 percent phase-in was included as part of the methodology. To estimate impacts under phase-in years, full impact results can be multiplied by the appropriate proportion of

the risk adjustment payments. For example, the first year risk adjusted payment phase-in level is 10 percent. Therefore, to estimate the impact under a 10 percent risk adjusted phase-in, the impacts can be multiplied by .10.

If our methodology did not include a transition period, payments to M+C organizations would decrease by approximately 5.7 percent. This is a revision over preliminary estimates of 7.6 percent, which were prepared using an earlier, more limited data set. The majority of M+C organizations would face payment decreases of between five and eight percent.

The table below presents the simulated impacts aggregated to our administrative regions. None of our regions will experience increased payments under the proposed system. The variation between regions is not considerable. Organizations in the Atlanta region will see an average .7 percent reduction, and organizations in the Seattle region will see less than a .4 percent reduction.

Table 4

Payment Summary for Selected M+C Organizations by HCFA Region

Region	Enrollees	Percent Difference (Phase-In)	Percent Difference (Full Impact)
Boston	359,819	-0.55%	-5.50%
New York	564,252	-0.35%	-3.47%
Philadelphia	583,740	-0.66%	-6.61%
Atlanta	895,021	-0.70%	-7.00%
Chicago	530,558	-0,50%	-4.97%
Dallas	472,627	-0.69%	-6.93%
Kansas City	154,223	-0.61%	-6.14%
Denver	128,069	-0.62%	-6.25%
San Francisco	1,710,117	-0.57%	-5.69%
Seattle	282,765	-0.35%	-3.45%
TOTAL	5,681,191	-0.57%	-5.74%

In addition, we simulated impacts by M+C organization enrollment size. Table 5 reveals that the variation in impact between the small M+C organizations and the large M+C organizations does not appear to be systematic. M+C organizations of all sizes are very close to the national average, although smaller organizations will experience a slightly higher reduction.

Table 5
Payment Summary for Selected M+C Organizations by Size of Enrollment

Enrollment Size	Enrollees	Percent Difference (Phase-In)	Percent Difference (Full Impact)
Less than 500	5,115	-0.71%	-7.10%
500-2,999	88,594	-0.81%	-8.10%
3,000-4,999	993,829	-0.69%	-6.87%
5,000-9,999	354,271	-0.62%	-6.22%
10,000-24,999	1,177,118	-0.58%	-5.79%
25,000-49,999	1,029,859	-0.54%	-5.41%
50,000-99,999	1,471,009	-0.52%	-5.23%
100,000 or more	1,455,843	-0.61%	-6.09%
TOTAL	5,681,843	-0.57%	-5.74%

5. M+C Organization Withdrawals

At the end of 1998, approximately 100 organizations dropped Medicare managed care contracts or reduced the number of counties in which a plan was offered. The result of these withdrawals was that nearly 50,000 beneficiaries were left with no remaining M+C plan in their county. Likewise, the analysis of 1999 health plan departures shows that approximately 79,000 additional M+C beneficiaries were forced to leave the program because there was no plan offered in their area.

Table 6 below shows the decline in beneficiaries' access to a M+C plan in their area (declining about 2 percentage points from the 1999 level of almost 70 percent).

Table 6

Percent of Beneficiaries with Access to M+C Plans

1999			2000		
Urban	**Rural**	**Total**	**Urban**	**Rural**	**Total**
84.2%	**22.5%**	**69.7%**	**82.0%**	**20.8%**	**67.7%**

Of the 71 counties that had an M+C plan in 1999 but will no longer have an M+C option in 2000, 11 were considered high payment counties. In fact, the average increase in 2000 for these 71 counties is 6.2 percent. The county in this situation with the greatest increase was Clallum County, in Washington State, which received a blended rate increase of 12.8 percent over their 1999 rate.

Plan decisions to withdraw from M+C do not appear to be caused only by changes in payment amounts. Payment is rising in all counties this coming year by an average of 5 percent, and will rise by as much as 18 percent in some areas. BBA payment reforms were designed to increase payment in counties that had the lowest rates, and therefore the fewest number of plans. Yet counties receiving the largest increases under the BBA payment system are experiencing the most disruption. Plan withdrawals

are affecting 11.1 percent of enrollees in counties where rates are rising by 10 percent, but affecting only 2.3 percent of enrollees where rates are rising by just 2 percent.

Table 7 shows the States with the largest percentage decrease since 1997 (the start of the M+C program) of Medicare beneficiaries with access to an M+C plan.

Table 7

States with Largest Percent Decrease in Access to M+C Option in 2000 from 1997

State	Total Medicare Population	Decrease in Beneficiaries	Percent Decrease in Beneficiaries
Utah	**207,838**	**183,541**	**88%**
Louisiana	**621,826**	**175,645**	**28%**
Virginia	**894,573**	**246,274**	**28%**
New Hampshire	**172,069**	**45,627**	**27%**
South Carolina	**575,890**	**130,118**	**23%**
Maryland	**652,599**	**119,392**	**18%**

While several States have experienced a significant loss of access to M+C plans, other States have seen access to M+C organizations increase. In addition, the M+C program continues to grow despite challenges that parallel those in the larger managed care market in the United States. As of January 2000, there were 6.2 million M+C enrollees representing over 16 percent of the more than 39 million seniors and disabled Americans in

Medicare. Total Medicare managed care enrollment has more than doubled in the past four years from 3.1 million enrollees at the end of 1995 to 6.9 million enrollees as of April 1, 2000. (Total managed care enrollees consist of M+C enrollees and enrollees in Medicare Managed Care Cost Plans, Health Care Prepayment Plans, and managed care demonstrations.) However, the rate of growth has dropped significantly from earlier periods, and has grown by only 1 percent per month the last several months.

Table 8 below shows the States with the largest percentage increase since 1997 (the start of the M+C program) of Medicare beneficiaries with access to an M+C plan.

Table 8

States with Largest Percent Increase in Access to M+C Option in 2000 from 1997

State	Total Medicare Population	Increase in Beneficiaries	Percent Increase in Beneficiaries
Maine	219,944	138,067	63%
Iowa	488,180	171,017	62%
South Dakota	122,220	118,493	29%
Oklahoma	519,239	114,185	24%
West Virginia	345,587	65,794	20%
North Carolina	1,149,374	54,040	18%

6. Premium Increases

In our Impact Analysis that accompanied the Interim Final Rule we stated that "Reductions in capitated payment amounts in what are now relatively higher payment areas may result in reduced benefits for beneficiaries." While higher premiums and reduced benefits were not intended effects of the BBA, they are also not surprising given the reduced payment increases in higher cost areas. While benefits, premiums, and cost sharing remained relatively stable in 1999, year 2000 has been different.

Analysis of the Adjusted Community Rate proposals submitted in July show that premiums for 2000 have increased, especially in rural areas. For example, in 1999, the enrollment-weighted average premium for a basic plan was $5.35. For 2000, this amount will almost triple to $15.84.

Table 9 shows the percent of M+C beneficiaries living in the designated areas that have access to a plan with the associated premium. While the percent of beneficiaries with access to zero dollar premium plans is expected to be reduced by more than 3 percentage points, the percent of beneficiaries that must pay a $40 - $100 premium has more than doubled. In 1999, only 50,000 Medicare beneficiaries lived in an area where the minimum premium is in the $80 to $100 range; however, in 2000, the number will rise to 207,000. The majority of these individuals (60 percent) are residents of rural counties.

Table 9

Percent of Beneficiaries Living in Designated Areas Having Access to an M+C Plan with Associated Premium

	1999			2000			
Premium Amount	**Urban**	**Rural**	**Total**	**Urban**	**Rural**	**Total**	**Total Percent Change**
$0	**79%**	**63%**	**78%**	**78%**	**40%**	**75%**	**-3%**
$0.01-$19.99	**1%**	**2%**	**2%**	**3%**	**11%**	**4%**	**2%**
$20.00-$39.99	**5%**	**14%**	**5%**	**9%**	**18%**	**9%**	**4%**
$40.00-$59.99	**4%**	**11%**	**5%**	**6%**	**17%**	**6%**	**2%**
$60.00-$79.99	**1%**	**8%**	**2%**	**1%**	**7%**	**2%**	**0%**
$80.00-$99.99	**0%**	**0%**	**0%**	**0%**	**0%**	**1%**	**1%**

In addition, access to a zero premium plan for rural beneficiaries will be reduced by almost 50 percent. In 1999, 1.3 million rural beneficiaries (63 percent of those with any plan available) live in an area with at least one zero premium plan; in 2000, only 784,000 rural beneficiaries, (40 percent of those with any plan available), will have such an option. One-half million fewer rural beneficiaries will have access to a zero premium plan.

7. Premiums in Areas with Only One Plan

Medicare beneficiaries who live in areas with only one plan will be particularly affected by premium increases. Approximately 8 percent of M+C beneficiaries (just over three million) live in areas with only one plan. Note also in Table 10

that of the 207,000 beneficiaries who live in areas where the minimum monthly premium available is over $80, 94 percent (over 195,000) live in areas with only one plan available. There will be a nearly six-fold increase from 1.6 percent to 9.3 percent in the percentage of beneficiaries who live in an area where the sole M+C plan available has a monthly premium in the $80 to $100 range.

Table 10

Medicare Beneficiary Population (Total), Access to Only One Plan

Minimum Premium	Year 1999		Year 2000	
	Beneficiaries	Percent	Beneficiaries	Percent
Zero	803,162	31.6%	599,553	28.4%
$0.01-$19.99	17,614	0.7%	-	0.0%
$20.00-$39.99	467,284	18.4%	410,662	19.5%
$40.00-$59.99	716,662	28.2%	683,029	32.4%
$60.00-$79.99	499,095	19.6%	220,237	10.4%
$80.00-$99.99	39,742	1.6%	195,432	9.3%
TOTALS	2,543,559	100%	2,108,913	100%

Premium increases in areas with only one plan will have the most pronounced impact in rural areas. From 1999 to 2000, roughly the same percentage of beneficiaries who live in rural areas will have only one plan available -- 28.4 percent and 29.6 percent in each year, respectively. However, Table 11 shows that

zero premium plans are becoming less widely available in rural areas. It also shows that there will be a significant increase in the number of rural Medicare beneficiaries whose only M+C option is a relatively high cost plan.

Table 11

Medicare Beneficiary Population (Rural Only)
Access to Only One Plan

Minimum Premium	Year 1999		Year 2000	
	Beneficiaries	Percent	Beneficiaries	Percent
Zero	271,833	37.7%	174,956	28.1%
$0.01-$19.99	17,614	2.4%	-	0.0%
$20.00-$39.99	96,131	13.3%	104,796	16.8%
$40.00-$59.99	135,440	18.8%	146,425	23.5%
$60.00-$79.99	160,647	22.3%	81,774	13.1%
$80.00-$99.99	39,742	5.5%	115,669	18.5%
TOTALS	721,407	100%	623,620	100%

8. Impact of BBRA

The Balanced Budget Refinement Act (BBRA) made two changes to the payment methodology established by the BBA. First, Section 512 of the BBRA introduced bonus payments for M+C organizations that enter previously unserved counties. These organizations will receive an additional 5 percent payment for the first 12 months and an additional 3 percent for the subsequent 12 months. The second change in section 517 of the

BBRA was to lower the reduction in the National per Capita Medicare +Choice Growth percentage from a 5 percent reduction to a 3 percent reduction in calculating the 2002 payment rates.

The Congressional Budget Office (CBO) estimated that the bonus payments would amount to additional payments of $.1 billion over three years. Our experience to date suggests that this figure may be high, as currently there are only five M+C organizations receiving bonus payments and very few pending applications from prospective M+C organizations that would be eligible for the bonus. However, there is an application on file from a prospective M+C organization that envisions expanding into a large number of previously unserved counties. If this organization is extremely successful in enrolling beneficiaries, the CBO estimate could in fact be a low estimate.

We estimate that lowering the reduction of the National per Capita Medicare+Choice Growth percentage in the year 2002 will provide an additional $80 million in payments to plans in 2002, and an additional $560 million over 5 years. Payments to plans in all subsequent years will be higher because of the effect of lowering the reduction on the baseline.

C. Response to Comments on Interim Final Rule

Since the publication of our June 26, 1998 interim final rule, we have implemented several significant changes aimed at alleviating unnecessary administrative burdens. Examples of

these changes include the less expansive provider participation requirements adopted in our February 17, 1999 rule, our December 1998 revisions to the QISMC standards as discussed below, and clarification of the attestation requirements through this final rule. Clearly the cumulative effect of these changes will be to reduce the administrative costs associated with these requirements. Although we continue to solicit quantifiable data that can help us to assess the costs of complying with particular provisions, we have not received any data in this regard. We remain particularly interested in detailed estimates of the administrative costs associated with the QISMC and HEDIS standards. Research of available literature/studies related to these administrative costs is presented below.

1. Quality Standards

The BBA codified many existing quality assurance requirements that had been established through operational policy letters and other guidance issued under the Medicare risk and cost contracting programs.

On September 28, 1998, we issued interim Quality Improvement Systems for Managed Care (QISMC) standards and guidance. QISMC is a system for ensuring that managed care organizations contracting with Medicare and Medicaid protect and improve the health and satisfaction of enrolled beneficiaries. It consists of a set of standards and guidelines developed around four

domains -- quality assessment and performance improvement, enrollee rights, health services management, and delegation.

QISMC was developed in conjunction with federal and state officials, beneficiary advocates and the managed care industry to develop a coordinated quality oversight system to reduce duplicative or conflicting efforts, emphasize demonstrable and measurable improvement, and avoid reinventing the wheel. QISMC standards represent the evolution of existing quality standards being used by commercial, Medicare and Medicaid health plans or managed care organizations. We believe QISMC incorporates the currently accepted quality assurance elements and provides safeguards for vulnerable Medicare and Medicaid populations enrolled in managed care.

We reviewed NCQA accreditation 1999 standards for their consistency with QISMC standards. This is an appropriate comparison because the National Committee for Quality Assurance has been recognized as a forerunner in assuring quality assurance in health plans through its accreditation processes, and development and implementation of HEDIS performance data reporting. Also, many Medicare+Choice organizations are NCQA accredited.

Our findings are provided in the table below, which was reviewed by NCQA representatives in order to assure the highest level of technical accuracy. In general, almost two-thirds of

NCQA accreditation 1999 standards were determined to be either consistent with variation or highly consistent or identical to QISMC standards.

Table 12

NCQA 1999	Overall	Domain 1 Quality Assessment & Performance Improvement	Domain 2 Enrollee Rights	Domain 3 Health Services Management	Domain 4 Delegation
Substantially Greater Than QISMC	12%	4%	11%	17%	--
Consistent with QISMC	62%	65%	68%	53%	100%
Substantially Fewer Requirements	26%	30%	21%	29%	--

Beneficiaries will benefit significantly from information available to them about the performance of their health plans as well as through improvements in the delivery of care and services that evolve out of on-going quality improvement projects under QISMC. Beneficiaries already have access to health plan performance and consumer satisfaction measures about the M+C organizations available in their area through our beneficiary education campaign and individual plan marketing.

We expect that as consumers become increasingly familiar with health plan performance and consumer satisfaction information, it will become an integral part of their decision-

making process, in addition to cost and benefits, for selecting their M+C organization. It is our intent that as consumers become better informed and decide not to select plans of lower quality, such plans will be motivated to initiate improvements in the quality of care they provide.

At the same time, we expect that plan's focus on one national and one plan-specific quality assessment and performance improvement project each year will improve the delivery of services to Medicare beneficiaries, especially beneficiaries suffering from chronic conditions. M+C organizations will need to be proactive in identifying and treating beneficiaries who suffer from medical conditions which are the focus of their quality assessment and performance improvement projects in addition to their HEDIS measures. This will ultimately lead to improved care and services for Medicare beneficiaries through the institutionalization of these practices.

a. QISMC Compliance

Purchaser demands have driven many managed care organizations to become NCQA accredited, implement quality measurement and performance improvement strategies, and report performance and satisfaction data. This has resulted in many managed care organizations becoming NCQA accredited, especially on the east and west coasts. We estimate that the cost of becoming NCQA accredited ranges between $300,000 - $500,000.

We do not believe that QISMC will present significant additional fixed costs for M+C organizations that have already received accreditation from the National Committee for Quality Assurance. While QISMC presents some subtle and significant differences from NCQA accreditation, we do not expect that organizations that have prepared for NCQA accreditation will incur significant additional costs to comply with QISMC. We recognize that there will be incremental costs associated with QISMC, such as costs associated with additional quality assessment and performance improvement projects, internal staff training expenses, and oversight and compliance.

In addition, we expect that some M+C organizations that are not NCQA accredited may incur higher costs to comply with QISMC than organizations in other parts of the country.

b. HEDIS Reporting

Since 1997, we have required M+C organizations to report HEDIS and consumer satisfaction data. Beginning in 1998, we required M+C organizations to begin reporting audited HEDIS data as a result of inconsistencies in HEDIS reporting.

We do not expect that requirements for reporting HEDIS and consumer satisfaction measures are inconsistent with expectations that private purchasers have access to health plan performance data (GAO, June 1998). As a result, we do not expect that organizations will incur significant new fixed costs as a result

of requirements to report performance measurement and consumer satisfaction data, since we expect that M+C organizations will use audited HEDIS data. However, we do recognize that there may be incremental costs to reporting audited HEDIS data in terms of additional processes, audit fees, etc.

In addition, requirements for M+C organizations to report audit HEDIS data will likely yield improved processes for collecting and reporting complete, accurate and timely data as a result of an independent third party review of their data collection, warehousing and production/reporting processes.

c. Quality Assessment & Performance Improvement Projects

We recognize that a significant difference between QISMC and NCQA accreditation 1999 is that QISMC is much more prescriptive in defining the type, scope and measurement of quality assessment and performance improvement projects. In response to industry concerns, we have reduced the number and delayed the timeframe for implementing quality assessment and performance improvement projects.

At the same time, specifying beginning and ending dates for QAPIs will ensure that plans do not become mired in projects that do not end. We expect that plans will focus their efforts on achieving results and institutionalizing improvements in the delivery of care, data collection and reporting and information system improvements gained from successful QAPI projects. Even

in instances where demonstrable improvements were not obtained, we expect that, in many cases, some improvement will result.

In addition, plans will have added incentives to initiate performance improvement projects that will lead to more cost-effective delivery of health care services, such as influenza immunization. For example, one national managed care organization increased the percentage of Medicare enrollees receiving flu shots from 27 percent to 55 percent in one year. The organization reported a reduction of about 30 percent in hospital admissions for pneumonia, savings of about $700,000, and fewer lives lost. (GAO, May 1996) We expect that investments in QAPI activities will lead to cost-savings over and above the initial investment.

We recognize that some high-performing managed care organizations will have less ability to achieve additional improvements in some areas. Some organizations will respond to incentives to select projects where results may be more easily obtainable. We continue to believe, however, that there are significant gains that remain to be made in the delivery of quality services.

We concur with industry comments that small plans may have difficulty in complying, since they may not have a statistically credible population for producing reliable and/or comparable measures. For example, a small plan with a healthier population

than average may not have sufficient instances of myocardial infarction for which beta-blocker treatment would be appropriate. We will work with these organizations to address these and other unique issues that may arise.

We believe that requiring plans to participate in at least one national and one plan-specific QAPI project annually and to demonstrate a 10 percent improvement in their QAPI is in the best interest of beneficiaries. These requirements will improve the quality of care and services delivered to Medicare and other populations served by the M+C organization, as performance improvement practices become routine.

d. Deeming

To avoid duplication of effort and unnecessary administrative burdens with respect to internal quality assurance requirements, we are recognizing accrediting by national, private accrediting organizations that we determine to be consistent with our QA requirements. We believe that this will significantly benefit a significant portion of M+C organizations that are already accredited, reducing costs, capitalizing on efficiencies, and avoiding duplicative processes.

2. Provider Procedures

Much less information is available about other requirements cited by some commenters as entailing significant administrative burdens. For example, we received many public comments regarding

provider participation requirements. We responded to many of those comments in our February 17, 1999, final rule (64 FR 7968), under which we narrowed many of the requirements set forth in our June 26, 1998 interim final rule (63 FR 34968). Modifications to the interim final rule included:

C Applying the applicable notice and appeal rights and consultation requirements only to physicians, as defined under section 1861 of the Act;

C Adopting a narrower interpretation of what constitute "rules regarding participation" to focus on whether a physician can participate under a given M+C plan;

C Clarifying that an M+C organization need only have reasonable procedures for notifying potential participating physicians of participation rules, which may include providing the information upon request;

C Clarifying that an M+C organization is not required to release information that an organization considers proprietary information;

C Clarifying that in the event that immediate changes are mandated through Federal law or regulation, an organization should be exempt from the requirement that written notice be provided before the changes are put into effect;

C Clarifying that there is no requirement that an organization obtain signatures acknowledging receipt of a notice of changes;

C Limiting the applicability of the appeals process to appealing adverse participation decisions;

C Clarifying that the availability of the provider appeals process applies only to cases involving suspension or termination of participation privileges, rather than including initial denials of an application to participate; and

C Clarifying that the information to be included in a notification of a decision to suspend or terminate an agreement with a physician is limited to information relevant to the decision.

Since publication of our February 17, 1999 final rule, we have subsequently communicated with several M+C organizations about the costs and benefits associated with the requirements included in this final rule. We believe that the steps taken in our February 17, 1999 final rule significantly reduced the burden on M+C organizations and also ensured that providers and beneficiaries receive the protections intended by Congress under the Act. For example, by narrowing the scope of the requirement for advance notice of changes in participation rules, an M+C organization need not prepare an advance notice for administrative and other changes that do not affect whether a

physician can participate in a plan. Notification of most changes made by a M+C organization can be made via usual communication methods, such as regular newsletters, rather than through the preparation of special mailings or other more burdensome methods.

In addition, the M+C organization must consult with the physicians who have agreed to provide services under the M+C plan offered by the organization, regarding the organization's medical policy, quality assurance program, and medical management procedures, and ensure that the following standards are met. We understand that these requirements are consistent with current operational practices by M+C organizations and pose little additional burden, and that the costs associated with incremental changes would be marginal.

We also understand that our requirements concerning credentialing processes and prohibitions on discrimination reflect current practices and similar requirements from other entities (for example, accrediting bodies) and do not impose additional burden.

3. Attestation Requirements

Similarly, commenters objected to attestation requirements as discussed in detail above (See Subpart K). To receive a monthly payment under subpart F, the chief executive officer (CEO) or chief financial officer (CFO) of a M+C organization must

request payment under the contract on a document that certifies the accuracy, completeness, and truthfulness of relevant data that we request. Such data include specified enrollment information, encounter data, and other information that we may specify. The CEO or CFO must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization, and the information relied upon by us in determining payment is accurate. The CEO or CFO must certify that the encounter data it submits under §422.257 are accurate, complete, and truthful. If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify the accuracy, completeness, and truthfulness of the data. In addition, the M+C organization must certify that the information in its ACR submission is accurate and fully conforms to the requirements in §422.310 in order to retain payment amounts below the amount of its ACR.

We understand that the collection and dissemination of this information by M+C organizations is undertaken in a manner that reflects an M+C organization's best efforts to ensure its accuracy, completeness, and truthfulness. Accordingly, we do not believe that this requirement imposes significant new burdens on an M+C organization that operates in good faith to comply with requirements under the M+C program. We realize that mistakes and

errors may occur even under an organization's best efforts, and these attestation requirements are not intended to penalize an M+C organization that operates in good faith. We believe these requirements are important to safeguard the integrity of the M+C program against those few M+C organizations that do not utilize the kind of business and operational practices of most M+C organizations. We also believe the requirements will provide an important tool for seeking out the few bad actors that could harm the M+C program, beneficiaries, providers, and other M+C organizations. As suggested by many commenters, we have revised the requirements to establish a "good faith" compliance standard as opposed to requiring an attestation of 100 percent accuracy for encounters and enrollment (payment related) data. We believe this change should alleviate commenters concerns over the undue financial burdens associated with attestation requirements.

VI. Other Required Information

A. Federalism Summary Impact Statement

On August 4, 1999, the president signed Executive Order 13132 (effective November 2, 1999) establishing certain requirements that an agency must meet when it promulgates regulations that impose substantial direct compliance costs on State and local governments, preempt State law, or otherwise have federalism implications. Any such regulations must include a federalism summary impact statement that describes the agency's

consultation with State and local officials and summarizes the nature of their concerns, the extent to which these concerns have been met, and the agency's position supporting the need to issue the regulation.

In this final rule, we are not promulgating any changes to the existing M+C regulations that meet any of the criteria mentioned above that would require the inclusion of a federalism impact statement under Executive Order 13132. However, the M+C interim final rule published on June 26, 1998 (63 FR 34968) did contain provisions that have a federalism impact, and we respond to comments on these provisions from States and other interested parties in this rule. Thus, in keeping with the intent of the Executive Order that we closely examine any policies that have federalism implications or would limit the policy making discretion of the States, we have prepared the following voluntary federalism impact statement.

In establishing the M+C program, the BBA included two provisions that have significant implications for States. First, under section 1855(a)(1) of the Act, an organization that wishes to participate in the M+C program generally is required to be organized and licensed under State law as a risk-bearing entity eligible to offer health benefits coverage in each State in which it offers an M+C plan. This statutory requirement is codified at §422.400(a) and §422.501(b)(1) of the M+C regulations, and we do

not believe it interferes with State functions or limits their policy making discretion. The requirement does not imposes any significant additional burdens on States, who for are already carrying out this licensing function. We received no comments from States on this provision.

The other aspect of the M+C statute and regulations that has significant federalism implications involves the Federal preemption provisions set forth under section 1856(b) of the Act and §422.402. Section 1856(b)(3)(A) provides for Federal preemption of State laws , regulations, and standards affecting any M+C standard if the state provisions are inconsistent with Federal standards. As discussed in the preamble to the interim final rule (63 FR 35012), and in section II.I of this preamble, we are applying this "general preemption" in much the same way that we previously applied Executive Order 12612 on Federalism. That is, State laws or standards that are more strict than the M+C standards would not be preempted unless they prevented compliance with the M+C requirements.

In addition to this general preemption, the Congress also provided (under section 1856(b)(3)(B) for a "specific preemption" whereby M+C standards supersede any State laws and standards in the following three areas:

- Benefit requirements;

• Requirements relating to the inclusion or treatment of providers; and

• Coverage determinations (including related appeals and grievance processes).

During the development of the June 26, 1998 interim final rule, we consulted with the National Association of Insurance Commissioners (NAIC) regarding the proper interpretation of these provisions. (The NAIC is the organization of the chief insurance regulators from the 50 states, the District of Columbia, and four U.S. territories.) The interim final rule contained an extensive discussion of this subject, including providing examples both of State laws that would be preempted under the M+C statue (such as "any willing provider laws" that would mandate the inclusion of specific types of providers or practitioners) and of State requirements that would continue to apply (such as a requirement that all providers and practitioners be licensed by the State and comply with scope of practice laws). We asserted our intention to adopt a narrow interpretation of the applicability of the three areas of specific preemption in order to ensure that any regulatory preemption of State law would be restricted to the minimum level necessary consistent with the BBA. State and local officials then had an opportunity to participate in the rulemaking process through their public comments on the M+C interim final rule.

For the most part, commenters representing State governments supported HCFA's narrow interpretation of the BBA's specific preemption provisions. (See section II.I of this final rule for a full discussion of comments on these provisions.) The most notable exception to this general support was the contention by one State that its mandatory drug benefit laws should not be preempted by the M+C benefit provisions; but we continue to believe that the specific preemption of "benefit requirements" under section 1856(b)(3)(B) of the Act clearly contradicts the State's contention. Moreover, we believe that our general approach is fully consistent with the "Special Requirements for Preemption" set forth in section 4 of Executive Order 13132. This section directs that an agency take action to preempt State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under Federal law or there is other clear evidence (such as an express statutory preemption provision) to conclude that Congress intended the agency to have the authority to preempt State law. It also provides that any regulatory preemption of State law be restricted to the minimum level necessary to achieve the objectives of the relevant statute. In conclusion, we believe that the concerns of State and local officials have been met to the greatest possible extent, consistent with the BBA's preemption provisions.

B. Waiver of Notice of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to afford a period for public comments before issuing a regulation in final form. However, we may waive that procedure if we find good cause that prior notice and comment are impractical, unnecessary, or contrary to the public interest. In addition, section 1871(b)(2)(B) of the Act provides that a notice of proposed rulemaking is not required if a statute establishes a specific deadline for implementation of a provision that is less than 150 days after the enactment of the statute in which the deadline is contained. Finally, Congress provides in certain cases by statute for the publication of a final rule without prior notice and comment.

For the most part, the changes to the M+C regulations set forth in this final rule with comment period result from our review of the public comments on the June 26, 1998 interim final rule that established the M+C program. Congress expressly authorized the publication of that final rule without prior notice and comment in section 1856(b)(1) of the Act. To the extent the provisions of this final rule respond to comments on that rule, they will have been subjected to prior notice and comment. However, as discussed in detail in section I.C of this preamble, this rule also makes conforming revisions to the regulations that are necessary to reflect changes to the M+C statute resulting from the BBRA (Pub. L. 106-113) which was

enacted on November 29, 1999. These changes in requirements and new requirements or provisions were enacted by Congress, and would be in effect without regard to whether they are reflected in conforming changes to the regulations text, since a statute controls over a regulation. In this final rule, we merely have revised the regulations text to reflect these new statutory provisions, as we interpret them. In most cases, the BBRA provisions have merely been incorporated virtually verbatim, with no interpretation necessary. Examples of such provisions include: the earlier availability of alternative Medicare enrollment options and the elimination of the lock-in rules for institutionalized individuals under section 501 of the BBRA, changes in the effective date of elections under section 502, the extension of Medicare cost contracts under section 503, the modification of the 5-year re-entry rule after contract terminations under section 513, flexibility to tailor benefits under an M+C plan under section 515, the delay until July 1 in the deadline for ACR submissions under section 516, the reduction in the adjustment in the national per capita M+C growth percentage under section 517, the new deeming provisions in section 518, the revised quality assurance requirements for PPOs under section 520, and the user fee provisions in section 522. For these types of provisions, we do not believe that publishing a notice a proposed rulemaking is necessary, nor would it be

practical given that a number of the provisions have already taken effect consistent with effective dates established under the BBRA. (For example, the changes in the effective date of elections and the new quality assurance requirements for PPOs took effect on January 1, 2000, and several other provisions were effective upon enactment of the BBRA.) In addition, we believe that it would be contrary to the public interest to delay implementation of these provisions until the process of publishing both a proposed and a final rule could be completed. Finally, we note that the BBRA was enacted on November 29, 1999; thus publication of a notice of proposed rulemaking is not required under section 1871(b) of the Act before implementing any new statutory provisions that took effect upon enactment or on January 1, 2000. Thus, we find good cause to waive proposed rulemaking for these provisions. We are, however, providing a 60-day period for public comment on those provisions.

In the case of two BBRA provisions, we have reflected our interpretation of the provisions in the regulations text. This interpretation is already in effect, and has been applied, as the provisions in question are already in effect. These provisions are section 501(c) of the BBRA, which permits an M+C organization that has reduced a plan service area to offer continued enrollment to current enrollees in all or a portion of the reduced areas, and section 512 that introduces "bonus payments"

to encourage organizations to offer M+C plans in areas without such plans. Both of these provisions are discussed in detail in section I.C of this preamble, and both required a limited amount of interpretation of the statute in order to implement the provisions on a timely basis. For example, with regard to the continuation of enrollment option (which was effective upon enactment of the BBRA), we have clarified that an M+C organization may offer enrollment in any plan it offers in the affected area, rather than solely the plan in which an individual was previously enrolled. This clarification results in greater flexibility for M+C enrollees and is consistent with our interpretation of a similar statutory provision affecting individuals with ESRD. Similarly, with regard to the bonus payment provisions (which took effect as of January 1, 2000), we have indicated that if an M+C organization or organizations offers two or more new plans simultaneously in a given area, the organization could receive the bonus payments for each new plan. We believe this interpretation of the statute clearly is consistent with legislative intent to promote the availability of more M+C alternatives for Medicare beneficiaries.

Policy clarifications of this limited nature were essential to implement these BBRA provisions in a clear and timely manner. Again, it would have been impractical and contrary to the public interest to proceed with proposed rulemaking before implementing

the interpretive policies linked with these provisions, nor is such rulemaking required under section 1871(b) of the Act. Thus, we believe that the "good cause" exemption to notice and comment rulemaking is equally applicable for these BBRA provisions as for the others discussed above, and the same 60-day period for public comment applies.

C. Responses to Comments

As discussed above, a limited number of the provisions set forth in this final rule are subject to a 60-day comment period. Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the **DATES** section of this preamble and, if we proceed with subsequent rulemaking, we will respond to the comments in that document.